Complete Summary

GUIDELINE TITLE

Thyroid cancer.

BIBLIOGRAPHIC SOURCE(S)

Thyroid cancer. Philadelphia (PA): Intracorp; 2005. Various p. [29 references]

GUIDELINE STATUS

This is the current release of the guideline.

All Intracorp guidelines are reviewed annually and updated as necessary, but no less frequently than every 2 years. This guideline is effective from April 1, 2005 to April 1, 2007.

COMPLETE SUMMARY CONTENT

SCOPE

DISCLAIMER

METHODOLOGY - including Rating Scheme and Cost Analysis RECOMMENDATIONS
EVIDENCE SUPPORTING THE RECOMMENDATIONS
BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS IMPLEMENTATION OF THE GUIDELINE
INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES
IDENTIFYING INFORMATION AND AVAILABILITY

SCOPE

DISEASE/CONDITION(S)

Thyroid cancer including

- Follicular cell
- Differentiated (papillary follicular variants)
 - Papillary
 - Follicular variant of papillary
 - Follicular and Hürtle cell
- Undifferentiated (or anaplastic)
- Parafollicular (medullary thyroid carcinoma [MTC])
 - Multiple endocrine neoplasms (MEN)
 - MEN IIa, pheochromocytoma, perithyroid carcinoma
 - MEN IIb, pheochromocytoma, mucosal neuromas, marfanoid habitus

- Connective tissue (lymphoma, sarcoma)
- Miscellaneous metastases (from breast, lung, kidney, melanoma)

GUIDELINE CATEGORY

Diagnosis Evaluation Management Treatment

CLINICAL SPECIALTY

Endocrinology Family Practice Internal Medicine Oncology Radiation Oncology Surgery

INTENDED USERS

Allied Health Personnel
Health Care Providers
Health Plans
Hospitals
Managed Care Organizations
Utilization Management

GUIDELINE OBJECTIVE(S)

To present recommendations for the diagnosis, treatment, and management of thyroid cancer that will assist medical management leaders to make appropriate benefit coverage determinations

TARGET POPULATION

Individuals with thyroid cancer

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis/Evaluation

- 1. Physical examination and assessment of signs and symptoms
- 2. Diagnostic tests:
 - Ultrasound (US)
 - Fine needle aspiration (FNA)
 - Scintillation scan with radionucleotides
 - Computed tomography (CT) scan without iodinated contrast medium
 - Magnetic resonance imaging (MRI)
 - Positron-emission tomography (PET)

 Laboratory tests: levels of serum thyroglobulin (Tg), thyroid hormone, calcitonin hormone, calcium, serum carcinoembryonic antigen (CEA); genetic testing, recombinant human thyroid-stimulating hormone (rhTSH) Thyrogen®

Management/Treatment

- 1. Preoperative levothyroxine suppressive therapy
- 2. Total or subtotal thyroidectomy
- 3. Regional lymph node dissection
- 4. Adjuvant radioactive iodine therapy for metastatic disease
- 5. Palliative combined therapy with chemotherapy and external beam radiation
- 6. Postoperative thyroid hormone replacement
- 7. Prophylactic total thyroidectomy to persons with (+) rearranged during transfection (RET) proto-oncogene mutations
- 8. 131 whole-body scans post treatment for surveillance
- 9. Physical therapy if indicated
- 10. Referral to specialists
- 11. Case management strategies, including case initiation, case management focus, and discharge

MAJOR OUTCOMES CONSIDERED

Utility of diagnostic tests

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Searches were performed of the following resources: reviews by independent medical technology assessment vendors (such as the Cochrane Library, HAYES); PubMed; MD Consult; the Centers for Disease Control and Prevention (CDC); the U.S. Food and Drug Administration (FDA); professional society position statements and recommended guidelines; peer reviewed medical and technology publications and journals; medical journals by specialty; National Library of Medicine; Agency for Healthcare Research and Quality; Centers for Medicare and Medicaid Services; and Federal and State Jurisdictional mandates.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Not Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not stated

METHODS USED TO ANALYZE THE EVI DENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus (Delphi)

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

A draft Clinical Resource Tool (CRT or guideline) is prepared by a primary researcher and presented to the Medical Technology Assessment Committee or the Intracorp Guideline Quality Committee, dependent upon guideline product type.

The Medical Technology Assessment Committee is the governing body for the assessment of emerging and evolving technology. This Committee is comprised of a Medical Technology Assessment Medical Director, the Benefit and Coverage Medical Director, CIGNA Pharmacy, physicians from across the enterprise, the Clinical Resource Unit staff, Legal Department, Operations, and Quality. The Intracorp Guideline Quality Committee is similarly staffed by Senior and Associate Disability Medical Directors.

Revisions are suggested and considered. A vote is taken for acceptance or denial of the CRT.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS.

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Comparison with Guidelines from Other Groups Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Diagnostic Confirmation

Subjective Findings

- Neck mass:
 - Often rapidly growing
 - May be painless or locally painful
- Shortness of breath
- Difficulty swallowing
- Changes in voice or speech
- Heat intolerance
- Palpitations
- Hemoptysis

Objective Findings

- Neck mass detected by imaging
- Dysphonia, dysphagia, and/or dyspnea
- Mass that moves on swallowing; suggests a mass originating in the thyroid
- Delphian node: midline mass above isthmus
- Single, fixed very firm nodule undergoing rapid growth; more likely to be malignant
- Vocal cord paralysis
- · Lateral cervical adenopathy

Diagnostic Tests

- Ultrasound (US)
 - To differentiate cystic versus solid mass(es)
 - Identify solitary versus multiple nodules
- Fine needle aspiration (FNA) biopsy with cytology
 - FNA biopsy is diagnostic procedure of choice.
- Scintillation scan (radioactive iodine uptake studies) with radionucleotides (Technetium-99m, ¹²³Iodine, ¹³¹Iodine)
 - Total body scans with radioactive iodine maximizes the potential to discover thyroid metastasis, "cold nodules"
 - Total body scans are advised yearly for first 3 years postthyroidectomy, then less frequently to monitor for recurrence.
 - Thyroid hormone should be stopped 4 weeks prior to scan.
- Computed tomography (CT) scan WITHOUT iodinated contrast medium (see the Intracorp Imaging guidelines)
 - CT is useful preoperatively to delineate tumor borders and structure.
- Magnetic resonance imaging (MRI) (see the Intracorp Imaging guidelines)

- MRI may be useful preoperatively to delineate tumor borders and structure.
- MRI and positron-emission tomography (PET) scans to detect metastasis
- PET also an alternative for post-treatment surveillance
- Laboratory tests:
 - Serum thyroglobulin (Tg) may be elevated, but this is not specific for cancer.
 - Post-op thyroid resection, however, this is important study
 - Tg level >10 ng/mL is a reliable indicator of local recurrent or metastatic disease.
 - Tg level <0.5 ng/mL after thyroid-stimulating hormone (TSH) stimulation greatly reduces need for further sentinel imaging studies.
 - Thyroid hormone levels have limited value in diagnosing cancer.
 - Calcitonin (CT) hormone- Normal values: Female: <14 ng/L; Male: <19 ng/L
 - Secreted by thyroid gland C-cells, high calcitonin indicates bone resorption inhibition
 - Calcium (Ca++) Normal values (adult): Non-ionized: 8.6 to 10.0 mg/dL; Ionized: 4.65-5.28 mg/dL
 - Hypercalcemia, reflecting metastatic bone disease, associated with mortality rates up to 50%
 - Serum carcinoembryonic antigen (CEA) levels
 - Usually elevated with medullary carcinoma
 - Useful as a marker for recurrent or metastatic disease
 - Genetic testing of siblings and offspring of patients with medullary carcinoma with defined RET gene mutations
 - RET = rearranged during transfection proto-oncogene germline mutations
 - Thyrotropin alpha or Thyrogen® [rhTSH] highly purified recombinant source of human thyroid stimulating hormone - may be used as an adjunctive diagnostic tool for serum thyroglobulin testing with or without radioiodine imaging for the detection of recurrent welldifferentiated thyroid cancer when any of the following medical necessity criteria are met:
 - Patient has a demonstrated inability to generate endogenous TSH secretion attributable to hypothalamic or pituitary disease
 - Patients in whom hypothyroidism is medically contraindicated due to conditions such as severe pulmonary or cardiac diseases OR
 - Patients with an undetectable thyroglobulin level while on thyroid hormone suppressive therapy to exclude the diagnosis of residual or recurrent thyroid cancer

Differential Diagnosis

- Simple versus toxic multi-nodular goiter
- Grave's disease (see the Intracorp guideline Hyperthyroidism)
- Hashimoto's thyroiditis
- Thyroid adenomas

- Inflammatory adenopathy
- Cysts, including thyroglossal and bronchial cysts and cystic hygroma
- Laryngocele
- Parathyroid tumors

Treatment Options

- Preoperative levothyroxine suppressive therapy
 - Care Setting: self-administered
- Surgical: thyroid excision
 - Total thyroidectomy
 - Subtotal thyroidectomy
 - Dichotomy is controversial (see the Intracorp guideline Thyroidectomy)
- Regional lymph node dissection: controversial for papillary, follicular, and medullary carcinoma
 - Care Setting: acute inpatient for differentiated tumors
- For metastatic disease: adjunctive radioactive iodine therapy is standard
 - Care Setting: clinic or free-standing outpatient; may begin in the acute inpatient setting immediately post-operatively
- For undifferentiated advanced thyroid carcinomas: palliative combined therapy with chemotherapy and external beam radiation (see the Intracorp guideline Chemotherapy)
 - Care Setting: clinic or free-standing outpatient unless patient severely deconditioned/acutely ill; then acute inpatient, subacute/skilled nursing facility inpatient, or hospice inpatient may be appropriate
- Postoperative thyroid hormone replacement (to suppress TSH production)
 - Care Setting: self-administered
- Prophylactic total thyroidectomy offered to persons found to have (+) RET proto-oncogene mutations
- i31 (radioactive iodine isotope) whole-body scans post treatment for surveillance
 - 2 to 4 months post-operatively AND 6 to 12 months post-operatively to check for metastasis
 - Two successive scans negative (-) for recurrent disease required for tentative diagnosis of remission

Duration of Medical Treatment

Medical - Optimal: 30 day(s), Maximal: 360 day(s)

Additional information regarding primary care visit schedules, referral options, specialty care, and physical therapy is provided in the original guideline document.

The original guideline document also provides a list of red flags that may affect disability duration, and return to work goals, including

- After fine needle aspiration
- After uncomplicated partial/total thyroidectomy

Note: Some patients with this condition may never return to work.

<u>Case Management Directives</u> (refer to the original guideline for detailed recommendations)

Case Initiation

Establish Case

- Document baseline information, history, key physical findings, patient's understanding, and safety factors.
- See Chemotherapy Chart in the original guideline document.
- The American Joint Committee on Cancer encourages use of the "TNM" classification system (T=primary tumor size; N=lymph node involvement; M=metastasis).
- Provide contact information for local and national support groups.
- Screen family members of patients with any multiple endocrine neoplasms (MEN) syndrome.

Coordinate Care

- Advocate for patient by managing utilization and charges.
- Document treatment plan.

Case Management Focus

Activity Deficit

- Assess need for and compliance with proper neck support using hands or bracing pillow postoperatively to avoid tension on sutures in semi-Fowler's positioning.
- Document activity alteration as none, mild, moderate, severe, dependent, or bed-bound (based on most recent performance status) and interventions required.

Chemotherapy Intolerance

 Assess status, acute versus chronic, of toxic side effects on rapidly growing tissues, including bone marrow, epithelium, hair, sperm, and document intervention recommended.

Hemodynamic Instability

• Document bleeding complications, severity, and intervention recommended.

Immune Compromised

 Document establishment of protective isolation measures for a white blood cells count (WBC) less than 1,000/mm³, implying dangerous susceptibly to infection.

Inadequate Nutrition

- Monitor serum calcium and phosphorus balance for adequacy of oral thyroid hormone supplementation.
- Assess need for supplemental vitamins containing ascorbic acid and thiamine.
- Evaluate presence and severity of swallowing difficulties postoperatively and nursing or therapeutic interventions necessary to expedite recuperation.
- Instruct in post-thyroidectomy nutrition modification to high daily calorie intake to compensate for increased metabolic activity that rapidly depletes glycogen reserves and the avoidance of stimulant intake.
- Encourage use of cold fluids, ice, and soft diet initially; progress diet cautiously.
- Assess for presence of surgical or radiation sequelae that hinder self-nutrition, including anorexia, bleeding, dry mouth, dysphagia, dyspnea, mucositis.
- Use optimal goal of remaining within 10% of pretreatment weight to document hydration and nutrition deficit as mild, moderate, severe and response needed.

Mental and Emotional Alteration

- Ensure accurate diagnosis of any change in mental status.
- Document baseline or optimal mental and emotional functioning and their alterations due to cancer presence, comorbidity, surgery, or treatments.
- Assess and respond appropriately to the degree of debility caused by alterations listed in the original guideline through benefit coordination or community resource activation.

Pain Control

- Determine need for analgesics or humidified oxygen (or air) for relief of pain and hoarseness post-operatively.
- Advise minimal talking postoperatively and report voice changes that occur.
- Instruct regarding need to maintain normal body temperature postoperatively by adjusting room temperature, taking cool baths or oral fluids, monitoring body temperature, providing dry linens as necessary.
- Document optimal pain management by characterizing severity and interventions undertaken to remedy or manage pain.

Oncologic Emergencies

- Immediately refer patient to attending physician or surgeon, or activate emergency medical technician (EMT) system as necessary, for hypocalcemia and tetany, infection respiratory distress (due to edema of glottis or laryngeal nerve damage), sensations of pressure at incision site (due to hematoma or hemorrhage), surgical wound disruption, or thyroid storm.
- Document presence of or developing oncologic emergencies and report to attending physician, surgeon, or activate EMT system as necessary.

Radiation Intolerance

- Document presence and severity of radiation side effects.
- Initiate early interventions for complications of radiation therapy.

Respiratory Instability

• Document respiratory deficit as mild, moderate, severe, and dependent, and respiratory rehabilitation enhancement measures.

Skin Integrity Deficit

- Assess frequency and duration of nursing interventions for wound care and teaching based on the type of surgical neck dissection.
- Document severity of skin integrity disruption.

Terminal Care

Document optimal comfort measures and palliative care initiatives.

Discharge

Discharge from Case Management (CM)

 Document return to independence or stabilized functional status and closing conversations with patient, caregiver, physician, pharmacist, and care providers.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate diagnosis, treatment, and management of thyroid cancer that assist medical management leaders to make appropriate benefit coverage determinations

POTENTIAL HARMS

Refer to the Case Management Focus section of the "Major Recommendations" field for information on potential complications and strategies to address them, or refer to the original guideline document.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1997 (revised 2005)

GUIDELINE DEVELOPER(S)

Intracorp - Public For Profit Organization

SOURCE(S) OF FUNDING

Intracorp

GUI DELI NE COMMITTEE

CIGNA Clinical Resources Unit (CRU) Intracorp Disability Clinical Advisory Team (DCAT) Medical Technology Assessment Committee (MTAC) Intracorp Guideline Quality Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Not stated

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

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Reprints of complete guideline content may be purchased for \$35.00 per title (plus tax in TX at 8.25% and CT at 1.0%). Please send e-mail request to lbowman@mail.intracorp.com.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Policies and procedures. Medical Technology Assessment Committee Review Process. Philadelphia (PA): Intracorp; 2004. 4 p.
- Online guideline user trial. Register for Claims Toolbox access at www.intracorp.com.

Licensing information and pricing: Available from Intracorp, 1601 Chestnut Street, TL-09C, Philadelphia, PA 19192; e-mail: lbowman@mail.intracorp.com.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on May 27, 2005. The information was verified by the guideline developer on June 7, 2005.

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